

treatment, without prejudice to or disclaimer of the subject matter contained therein, as outlined in Appendix A, entitled "Claim Amendments", attached herewith.

REMARKS

Claims 26-31 are currently pending in the present application, which are directed to a process for preparing a storage-stable topical composition for treating a skin disorder or condition. Claims 1-25 and 32-37 are cancelled and the Examiner's rejections against those claims are now moot. The amendments to the claims do not introduce new matter within the meaning of 35 U.S.C. §132. Accordingly, entry of the amendments is respectfully requested.

1. Rejection of Claims 1-12, 14-26, 30-34, and 36-37 under 35 U.S.C. §102(b)

The Official Action states in the relevant part that claims 1-12, 14-26, 30-34, and 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Baroody et al. (US 6,117,843).

As the basis of the rejection, the Official Action states in relevant part:

...claim 1 is present as a product by process, where the process limitations do not carry patentable weight...Instant claims, as presented do not distinguish from the composition of Baroody, in terms of the final viscosity. Accordingly, whatever the initial viscosity of the benzoyl dispersion is, the resulting product (claimed) is indistinguishable from the composition of Baroody.

...Applicants argue that the final viscosity of the composition is lower than the viscosity of benzoyl peroxide dispersion, whereas in contrast, Baroody specifically state that the benzoyl peroxide component itself may be maintained at a relatively low viscosity while the final topical composition (which is at a different pH) will have a relatively higher viscosity...

Applicants' arguments have been considered but not found persuasive because instant claim 1 does not recite a specific final viscosity so as to distinguish the composition from that of Baroody. Accordingly, even though the claims have been amended to include the process of preparation, the resulting composition (from the claimed process steps) is indistinguishable from the composition of Baroody...With respect to the arguments regarding the final viscosity, in addition to the fact that instant claims do not recite any specific viscosity, the teachings of Baroody that the final viscosity is higher is not an absolute requirement for the composition. Instead, Baroody only states that the viscosity may be adjusted to higher viscosity. Hence the rejection has been maintained.

Applicants respectfully traverse this rejection. The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990). Moreover, the rule of law requires that the Examiner must consider a reference *in its entirety* in determining the scope and content of the reference. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, (Fed. Cir 1983), *cert. denied*, 469 U.S. 851 (1984). Thus, the Examiner must acknowledge any disclosure in the reference that *teaches away* from the present invention. *Id.*

With respect to the rejection of claims 1-12, 14-25, 32-34, and 36-37, applicants respectfully traverse this rejection. However, solely to remove the basis for this rejection, applicants have canceled claims 1-12, 14-25, 32-34, and 36-37, without prejudice to or disclaimer of the subject matter contained therein, rendering the basis for

these rejections moot.

Regarding pending claims 26, 30, and 31, applicants respectfully assert that, not only does the Baroody reference not teach each and every element of the presently pending claims, but the Baroody reference actually teaches away from the presently pending claims.

In particular, the presently pending claims relate to a process for preparing a storage-stable topical composition that requires mixing a benzoyl peroxide intermediate dispersion having a viscosity of 60,000 to 250,000 centipoises and a clindamycin intermediate solution, such that the final composition has a viscosity of 50,000 to 200,000 which is *lower than the viscosity of the benzoyl peroxide dispersion before mixing*. This final viscosity that is lower than the viscosity of the benzoyl peroxide dispersion demonstrates that the resulting composition prepared by the presently claimed process are easier to mix together, contain less degradates and have a greater degree of uniformity than those compositions previously known in the art, including those from the Baroody reference (see, at page 15, lines 4-9 of the instant application).

In contrast, at col. 4, lines 44-52, Baroody specifically disclose a process for preparing the topical composition by combining or admixing an aqueous gel suspension of benzoyl peroxide with an aqueous solution of a clindamycin salt or ester, where the benzoyl peroxide suspension is initially combined with a gelling agent to form a first component of a two-component kit. The gelling agent is selected to have a *reduced viscosity* at the pH of the first component and *an increased viscosity* at the stage of the final product obtained by the combination. Similarly, at col. 6, lines 3-6, Baroody specifically disclose that "when the benzoyl peroxide component is combined with the

clindamycin component, the resulting combined product will have an increased pH resulting in *enhanced viscosity* within the range set forth above.” (Emphasis added) Further, at col.6, lines 22-23, Baroody discloses that “a *beneficial increase* in viscosity can be achieved”. (Emphasis added)

Accordingly, not only does the Baroody reference fail to disclose the requirement of the presently pending process claims that the final composition made by the claimed process has a viscosity *lower* than the viscosity of the intermediate benzoyl peroxide dispersion, but the Baroody reference teaches the exact opposite, requiring the final composition to have a viscosity *higher* than the benzoyl peroxide intermediate composition.

In addition, applicants do not agree with the Examiner’s assertion, at page 6, lines 4-6, in the Official Action that Baroody does not teach the higher viscosity of the final product as an absolute requirement of the composition, only stating that the viscosity may be adjusted to higher viscosity.

The Examiner must consider a reference *in its entirety* in determining the scope and content of the reference. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, (Fed. Cir 1983), *cert. denied*, 469 U.S. 851 (1984). From the teachings of the Baroody reference, at col.3, lines 7-9 and 29-36; at col. 4, lines 28-32 and 44-52; at col. 5, lines 48-57; at col. 6, lines 1-6, 22-26 and 49-50, it is very clear that Baroody teaches, in its entirety, that the relatively lower viscosity of the benzoyl peroxide suspension, and the relatively higher viscosity of the final composition, is very beneficial and essential to preparing the desired compositions. Baroody specifically discloses, at col. 5, lines 60-64, that “the viscosity of the benzoyl peroxide component will be below about 9×10^4

cp...more preferably being in the range of 6.5×10^4 cp to 8.5×10^4 cp, while the viscosity of the final topical composition product will be in the range from 7×10^4 cp to 12×10^4 cp, more preferably being in the range of 8×10^4 cp to 10×10^4 cp". (Emphasis Added) This clearly shows that the Baroody reference requires a higher viscosity of the final composition.

As such, the Baroody reference does not anticipate the presently pending claims because it 1) fails to disclose each and every element of the presently pending claims as required by *Verdegaal Bros. v. Union Oil Co. of California*; and 2) actually teaches the exact opposite of, and thus teaches away from, the presently pending claims.

Accordingly, applicants respectfully request the Examiner to reconsider and withdraw the rejection of presently pending claims 26-31.

2. Rejection of Claims 13, 27-29, and 35 under 35 U.S.C. §103(a)

The Official Action states in the relevant part that claims 13, 27-29, and 35 are rejected under 35 U.S.C. 103(1) as being unpatentable over Baroody et al. (US 6,117,843).

As the basis of the rejection, the Official Action states in relevant part:

...With respect to the viscosity of initial benzoyl peroxide dispersion and final viscosity of the composition (claims 9-11 and claims 26-34), Baroody teaches a range of viscosities of benzoyl peroxide dispersion and the final viscosities, that overlap with the claimed viscosities and hence the argument is not persuasive. Further, Baroody recognizes that viscosity achieved by the addition of a gelling agent such as carbomer, is a function of pH (see col. 5, L 45-67, table 3). Baroody suggest adjusting the viscosity of the benzoyl peroxide by choosing the appropriate amounts of gelling agents and pH. While the reference teaches that one "may" choose to have a final viscosity higher than the initial viscosity, applicants have not show that the viscosities of the Baroody

compositions are different from that of instant. Accordingly, in the absence of any unexpected results comparing the compositions of Baroody with that of the instant claimed composition as well as process, it would have been obvious for one of ordinary skill in the art at the time of the instant invention to choose the appropriate amounts of gelling agents and pH so as to adjust the viscosity of the initial benzoyl peroxide dispersion and that of the final composition and still achieve the claimed stability.

Applicants respectfully traverse this rejection.

The Examiner has failed to establish a *prima facie* case of obviousness against the presently rejected claims. To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court very recently held in *KSR International Co. v. Teleflex Inc. et al.*, Slip Opinion No. 04-1350, 550 U. S. ____ (April 30, 2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR, supra*, slip opinion at 13-15.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the

vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Applicants hereby incorporate by reference in its entirety the discussion in Section 1 above regarding the scope of the presently pending claims, the scope of the Baroody reference cited by the Examiner, and the differences between the two.

As noted above, the Baroody reference does not teach, disclose, or render obvious any of the presently pending claims because it fails to disclose the requirement of the presently pending claims that the claimed process results in a final composition having a viscosity lower than the viscosity of the intermediate benzoyl peroxide dispersion. Instead, Baroody actively teaches the exact opposite, requiring the final composition to have a viscosity *higher* than the benzoyl peroxide intermediate composition. This would motivate one skilled in the art who wishes to invent a storage-stable clindamycin topical composition, to avoid taking the opposite relative viscosity between the benzoyl peroxide and the final composition as in the presently pending claims.

Further, the Baroody reference contains no suggestion or incentive to motivate the Baroody reference teachings to reach the presently claimed process. Accordingly, there is no reason for one skilled in the art to take the presently claimed process to prepare the composition of clindamycin and benzoyl peroxide, where the viscosity of the final composition is relatively lower than that of the benzoyl peroxide, which is the exact opposite of the teachings in the Baroody reference.

In addition, applicants submit that the teachings of the Baroody reference are not such general conditions for the presently pending claims as recited in *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), but instead are the opposite conditions teaching away from the presently pending claims. Accordingly, it is not appropriate for the Examiner to recite *In re Aller* to negate the nonobviousness of the presently pending claims 26-31.

As such, the Baroody reference does not teach, disclose, or render obvious the presently pending claims 26-31. Accordingly, applicants respectfully request the Examiner to reconsider and withdraw the rejection of presently pending claims 26-31.

CONCLUSION

Based upon the above remarks, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw the outstanding rejections and allow all pending claims 26-31. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if she has any questions or comments.

Respectfully submitted,
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